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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,567	07/31/2003	Paul Workman	CCI-026US	2601

959 7590 01/26/2007

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TY

Office Action Summary	Application No.	Applicant(s)	
	10/632,567	WORKMAN ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,22-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,22-25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18,22-25,27 and 28 are pending in the application. The amendment to title has been acknowledged. It is also acknowledged that applicant asserts that a certified copy of the foreign Great Britain patent application will be filed.

Response to Arguments

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Applicant's arguments filed 11/21/06 have been fully considered but they are not persuasive.

3. Claims 1-18,22-25,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumont et al. (US 6,413,974) in view of the combined teachings of Dumont et al. (US 6,399,633) and Carlson et al. (*Cancer Res.* **1999**, *59,* 4634-4641) as previously stated in the office action mailed 6/22/06.

4. Applicant asserts that the Dumont et al. (US 6,399,633) reference teaches the assessment of phosphorylated erk1 and erk2 upon exposure to flavopiridol but that the reference concludes that flavopiridol has not effect on erk1 and erk2 phosphorylation.

5. The Dumont et al. (US 6,399,633) reference was used to show that cyclin dependent kinase (cdk) inhibitors are used to monitor the levels of phosphorylated Rb and levels of phosphorylated erk1 and erk2. The instant claims are drawn to the

method of monitoring the activity of roscovitine (a cdk2 and cdk4 inhibitor) and detecting the presence of phosphorylated erk1 and erk2 and not to the method of phosphorylating erk1 and erk2 via administration of roscovitine. Applicant asserts that roscovitine uniquely induces the phosphorylation of erk1 and erk2 but unique properties of compounds do not impart patentability, whereas the property is inherent to the compound. Also, only a property of the compound and not a specific method step, such as detecting the phosphorylation of erk1 and erk2 can be used to distinguish over the prior art. Dumont et al. (US 6,399,633) explicitly discloses that the levels of phosphorylated Erk1 and Erk2 were measured upon administration of flavopiridol, a cdk2 and cdk4 inhibitor, with the phosphorylation-specific antibody (column 3, lines 3-5). The method step of detecting the presence of phosphorylated erk1 and erk2 may reveal that there may be no phosphorylated erk1 and erk2 present. Although the disclosure reveals that the cdk inhibitor, flavopiridol, has not effect on MAP kinase phosphorylation, the method of monitoring the phosphorylation or Erk1 and Erk2 is clearly stated (column 10, lines 24-45).

6. Applicant asserts that Dumont et al. (US 6,413,974) and Carlson et al. (*Cancer Res.* **1999**, *59,* 4634-4641) fail to account for the deficiencies of the Dumont et al. (US 6,399,633) reference, that they fail to discuss cdk inhibitors in the context of erk1 and erk2 and that the combination of the references do not provide for the expectation that roscovitine would induce phosphorylation of erk1 and/or erk2.

7. Cdks control the cell cycle progression along phosphorylated serine and threonine amino acid residues and the Carlson et al. (*Cancer Res.* **1999**, *59,* 4634-

4641) reference was provided to show that it is obvious to monitor the phophorylation at the serine 780 Rb species upon the administration of a cdk inhibitor, in this case flavopiridol.

8. Dumont et al. (US 6,413,974) discusses that roscovitine is a cdk2 and cdk4 inhibitor (column 13, lines 28-40) as is flavopiridol. Therefore it would be obvious to employ cdk inhibitor equivalents to monitor the same conditions/variables and the Dumont et al. (US 6,413,974) reference was used as such.

9. The combination of the references encompasses the instant claims where it would be obvious for one ordinarily skilled in the art to employ the dk2 and cdk4 inhibitor roscovitine as a cdk inhibitor equivalent/substitute to detect the presence of phosphorylated of erk1 and/or erk2. Also, it is unnecessary for the examiner to provide for the expectation that roscovitine would induce phosphorylation of erk1 and erk2 as obviousness does not require absolute predictability.

Conclusion

No claims are allowed at this time.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
January 11, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER